to-severe BPH completed three disease-specific instruments at baseline and at follow-up visits: the International Prostate Symptom Score (IPSS, a 7-item urinary symptom severity scale), the BPH Impact Index (BII, a 4-item well-being scale associated with BPH) and the PPSMQ (a 12-item instrument measuring patient satisfaction in control of urinary symptoms, strength of urinary stream, pain of urination and effect on usual activities due to the pharmacotherapy). The psychometric performance, including reliability, validity and responsiveness, of the PPSMQ was analyzed. **RESULTS:** The mean age of the study sample was 66.7 years (n = 879). The PPSMQ demonstrated good internal consistency (Cronbach's alpha = 0.88 to 0.96) and reliability (intraclass coefficient = 0.37 to 0.40). Convergent validity of the PPSMQ subscale and total scores measured by the Pearson coefficient ranged from 0.48 to 0.58 for the IPSS and 0.31 to 0.45 for the BII, suggesting correlations between the PPSMQ and another two logically-related instruments. The PPSMQ also demonstrated discriminant validity against the IPSS, IPSS QoL item and BII (F = 52.5, 42.3, and 26.9, respectively, p-values < 0.001). The PPSMQ detected treatment differences between the monotherapy and combination therapy arms: total scores at baseline for the combination therapy, dutasteride and tamsulosin treatment groups were 25.6, 25.8, and 25.7 (higher scores indicating lower satisfaction), respectively; at two years, the scores were 17.8, 20.3, and 20.4, respectively. **CONCLUSION:** The PPSMQ demonstrated good reliability, validity and responsiveness in measuring patient satisfaction with the pharmacology treatments for BPH. The PPSMQ may be an important addition to the existing outcome measures used to assess BPH symptoms and their treatments.

PUK22

ASSESSING PATIENT DESCRIPTIONS OF LOWER URINARY TRACT SYMPTOMS (LUTS) AND PERSPECTIVES ON TREATMENT OUTCOMES FOR THE DEVELOPMENT OF A NEW LUTS PATIENT REPORTED OUTCOME TOOL

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OBJECTIVE: Although various instruments have been used to assess the prevalence of LUTS, the interpretability of questions from a patient perspective has not been assessed. There is a need for qualitative research to inform the development of a patient reported outcome (PRO) tool that assesses all LUTS. **METHODS:** A series of eight focus groups and 66 cognitive debriefing interviews were conducted to elicit patient descriptions of urinary symptoms and to assess treatment-seeking behavior and treatment outcomes. Participants with a range of LUTS were recruited from urology clinics and community settings in different USA geographic regions. Trained interviewers conducted each session following semi-structured interview guides. Content and descriptive analyses were performed. **RESULTS:** A total of 129 people (66 men, 63 women) participated. Mean age was 54 (26–80 y); 71% were white. Mean symptom duration was 7 years for men; 15 years for women. A wide range of LUTS were reported with participants generally understanding and agreeing on the words used to describe most LUTS. There were no differences in terminology used by clinical and community participants. Some difficulty describing bladder area pain, split stream, terminal dribble and post-micturition dribble was noted. Most participants identified with the word "bother" and thought it was important to assess both the frequency and bother of each symptom. Reasons for seeking care included symptom bother and fears about cancer and bladder infections. When asked to describe a positive treatment outcome, 64% of participants responded that a 50% improvement in at least one LUTS would be meaningful. A draft LUTS tool was developed based on patient feedback. **CONCLUSION:** There is a need for a new PRO tool to assess the frequency and bother of all LUTS in terms understood by patients. A new LUTS PRO tool was developed to include the patient perspective and is undergoing validation.

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EVALUATION OF FACE AND CONTENT VALIDITY OF NOCTURIA QUALITY OF LIFE QUESTIONNAIRE (N-QOL)

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OBJECTIVE: Nocturia Quality of Life (N-QOL) questionnaire is a self-administered, nocturia-specific, QoL instrument developed to examine QoL impact of nocturia in male patients. This study was designed to evaluate content and face validity of the N-QOL in female patients. **METHODS:** Twenty women (mean age 59 years; range 27–83) diagnosed with nocturia (≥2 voids/night) were recruited through U.S. urology clinics. To establish content and face validity, the items and response options in the questionnaire must be considered relevant and comprehensive. The N-QOL questionnaire was evaluated using 2 methodologies. First, 15 patients provided information on their experiences of the impact of nocturia on their QoL and reported the most bothersome consequences of nocturia in a focus group format. Patient responses were thereafter compared with N-QOL items to evaluate how well they reflected the N-QOL concepts being measured. Second, five patients directly evaluated the N-QOL in an interview format using standardized cognitive debriefing methodology. **RESULTS:** Of the 20 participants (80% Caucasian, 10% African-American, 10% Hispanic), 45% had their condition for more than 5 years (45% had 3 voids/night and 25% ≥4 voids/night). Seventy percent had nocturia secondary to OAB, and 30% were currently taking prescription medication for the underlying cause of their nocturia. Disrupted sleep was the most bothersome consequence of nocturia, which resulted in sleeping longer into the daytime hours, being too tired to exercise, eating at night, weight gain, difficulty concentrating, and reduced productivity during daytime. This corresponded well with N-QOL concepts. Directly evaluated the N-QOL was found simple, clear, easy to complete, and comprehensive. **CONCLUSION:** The N-QOL has face and content validity in female nocturia patients, with sleep disruption causing severe impact on daytime activities, as the most bothersome consequence. The N-QOL items and response options are relevant and comprehensive for assessing the impact of nocturia on QoL of female patients.